

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

SHIRE LLC, et al.,

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS, LLC, et al.,

Defendants.

C.A. No.: 2:11-cv-03781(SRC)(CLW)
(CONSOLIDATED)

SHIRE LLC, et al.,

Plaintiffs,

v.

WATSON LABORATORIES, INC. et al.,

Defendants.

C.A. No.: 12-CV-83

DOCUMENT FILED ELECTRONICALLY

**REPLY BRIEF IN SUPPORT OF
DEFENDANTS' NOTICE OF APPEAL PURSUANT TO L. CIV. R. 72.1(c)(1)**

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Shire's opposition to Defendants' appeal seeks to prevent this Court from deciding the on-sale bar of the '253 Patent on the merits. Relying on Local Rule 3.7, Shire argues that Defendants were not sufficiently diligent in discovering the prior sale evidence, and then not quick enough to file a motion. Of course, Shire makes no mention of the fact that Shire took from February 2012 until the end of June 2013 to produce some of the documents at issue. If Shire is considered to have been diligent and fair in taking over a year to produce the relevant documents, it cannot be concluded that Defendants were dilatory in moving to amend their invalidity contentions within months of receiving those documents.

Moreover, the issue of diligence must be viewed in the context of a single fundamental economic reality: Shire enjoys monopoly profits on a drug for which no competition is allowed. For Shire, the only thing better than indefinite delay would be a ruling that preserves Shire's monopoly on the product at issue without ever having to defend that monopoly on the merits. In contrast, Defendants – which cannot sell a competing product – have nothing to gain by delay.

Any perceived lack of "diligence" can only be explained by the fact that Defendants were moving as fast as reasonably could be expected given the enormous volume of discovery material, the complexity of the issues, and the obstacles to discovery put in place by Shire. There is a great difference between acting with diligence and acting precipitously. Defendants' own economic self-interest dictates that they move as fast as possible, recognizing that they have many complex issues and mountains of material to digest, as well as obligations to the Court pursuant to Rule 11, and obligations to prove their invalidity defenses by clear and convincing evidence.

Shire presents even the simplest of issues in a misleading fashion. For example, in Defendants' opening brief, Defendants observed that AMRI was represented by the Frommer firm in responding to discovery requests. As if to challenge that fact, Shire offers a sentence in a footnote: "Moreover, third party AMRI had its own counsel from the LeClair Ryan law firm." (Shire Br. at 1, fn 2.) But even that seemingly simple statement is misleading because it fails to

explain that LeClair Ryan was co-counsel along with Frommer, which was Defendants' point all along: "Please be advised that Frommer Lawrence & Haug, LLP ("FLH"), along with LeClair Ryan, represent AMRI with respect to *all matters related to this litigation*, including this subpoena." (Ex. J to D.I. 462, April 17, 2012 letter from S. Kuzmich at FLH, responding to Defendants' April 2012 document subpoena to AMRI (emphasis added).)¹

Shire was likewise misleading in its discussion of the information available to Defendants prior to the motion to amend their invalidity contentions. Contrary to Shire's argument, Defendants did not have sufficient information to assert the on-sale bar for the '253 Patent after receiving the documents identified below – because critical information was missing:

- 8K and 10Q documents: The 8K and 10Q documents merely identified the *existence* of contracts with various potential manufacturers. (Shire Br. at 5-6.) The 8K and 10Q not only fail to identify any dates on which the suppliers actually sold or offered to sell lisdexamphetamine dimesylate, they also fail to even identify the drug by its chemical name. (D.I. 396 at 6-7; D.I. 425, Oct. 22, 2013 Oral Argument Tr. at 28: 9-19.)
- Shire's New Drug Application: The cited pages from Shire's NDA disclosed only the names and addresses of potential manufacturers. (Shire Br. at 6.)
- AMRI Purchase Requisition Form: The AMRI requisition form did not mention lisdexamphetamine dimesylate by name, and did not reflect a commercial sale of this compound. At best, the form represents an offer to buy, not an offer to sell, which cannot support an on-sale bar. Linear Tech. Corp. v. Micrel, Inc., 275 F.3d 1040, 1052 (Fed. Cir. 2001) (reversing on-sale bar; entry of purchase orders into an order tracking system did not constitute acceptance of an offer to buy). Nor did the form identify the highly specific requirements of certain claims of the '253 Patent (e.g., particle size).

Like the first few pieces of a puzzle, these earlier documents might have indicated that there was a picture of something; but they were not enough to determine what the picture was.

Helsinn Healthcare S.A. v. Dr. Reddy's Laboratories, Inc., CIV. A. 11-3962 (MLC), 2013 WL

¹ Similarly misleading is Shire's statement that Defendants relied on new evidence in their appeal brief. (Shire Br. at 3-4.) Shire is mistaken. All evidence cited in the appeal brief was before Judge Waldor (Exs. B, D-F are cited in the Proposed Amendment to Invalidity Contentions, which appears as Ex. D to D.I. 383; Ex. B also appears as Ex. F to D.I. 396; Ex. C is an exact copy of Ex. B; Ex. G is referenced in D.I. 383 at 5; Ex. I is referenced in D.I. 383 at 5 and D.I. 396 at 6; Ex. J is referenced in D.I. 383 at 5 and D.I. 396 at 5; Ex. K is referenced in D.I. 396 at 5; Ex. L is referenced in D.I. 383 at 10 and D.I. 396 at 1; and Ex. M is incorporated by reference in D.I. 383 at 4.)

3336859, at *4 (D.N.J. July 2, 2013) (“That pieces of the puzzle might have been revealed at earlier times does not mean that a complete picture was likewise available.”) Additional documents and depositions were, therefore, necessary to elucidate the basis of and support for the on-sale bar defense. Even Judge Waldor recognized the possibility that additional information beyond these documents might have been required to seek amendment of Defendants’ contentions. (D.I. 456 at 5, referring to documentation that “should have led” Defendants to the information needed to support the on-sale bar.)²

But contrary to Shire’s arguments, Defendants did not wait eight months after receipt of the first of the additional documents to seek to amend their contentions. (Shire Br. at 9.) Rather, after being requested in early 2012, the additional documents were withheld for close to a year and then haltingly produced by Shire (in some cases, never produced by Shire), and third parties (as shown below), despite Defendants’ extensive diligence and follow-up over many months. (See, e.g., Opening Br., Ex. J.)

Document	Third Party Production Date	Shire’s Production Date
AMRI/New River API Supply Agreement	May 30, 2013	June 28, 2013
Cambrex/New River API Quality Agreement	Jan. 11, 2013	Never produced by Shire
Patheon Batch Production Report		Mar. 29, 2013
Patheon Quality Operations Report		Mar. 29, 2013
AMRI Invoices	Sept. 17, 2013	Never produced by Shire

Thus, Defendants were diligent in pursuing leads and seeking discovery. But Shire – which had an economic interest to delay – did not provide the necessary documents until nearly a year later. Therefore, the timing of the Defendants’ requested amendment was not “within the

² Shire’s citations to the patents in-suit are unavailing. Defendants could not presume that terms and codes used by the patents were consistent with how third parties used them.

reasonable control of the party responsible for it,” which is a key factor in demonstrating good cause to amend. Helsinn, 2013 WL 3336859, at *3 (citing Oy Ajat, Ltd. v. Vatech Am., Inc., CIV. No. 10-cv-48, 2012 WL 1067900, at *20-21 (D.N.J. Mar. 29, 2012)); see also Symantec Corp. v. Veeam Corp., No. C 12-00700 SI, 2013 WL 3490392, at *2-3 (N.D. Cal. July 11, 2013) (granting motion to amend where plaintiffs delayed production for ten months, and rejecting plaintiffs’ argument that the documents cited in the proposed contentions were publicly available, instead finding that defendant “needed non-public documents to determine whether it could claim in good-faith that the [plaintiffs’] products invalidated the patent.”); AS Am., Inc. v. Masco Corp. of Indiana, CIV. 13-05 (JBS/JS), 2013 WL 4084237, at *2-3 (D.N.J. Aug. 13, 2013) (granting motion and not requiring “perfect diligence” because Defendant did not “simply sit on its hands”).³

As the Court observed in Helsinn, “It is reasonable to conclude . . . that [Defendant] was not able to formulate a ‘comprehensive story of Plaintiffs’ . . . violation of the on-sale bar’ . . . until Plaintiffs had completed their document production.” 2013 WL 3336859, at *4. Here, Defendants were able to put the new pieces together on July 30, 2013, and continued to request confirming invoices from AMRI.⁴ Defendants then asked for Shire’s consent to amend on August 23, 2013.⁵

³ Here, unlike the circumstances in Jazz Pharm., Inc. v. Roxane Labs., Inc., CIV. No. 10-6108, 2013 WL 785067 (D.N.J. Feb. 28, 2013) and Jazz Pharm., Inc. v. Roxane Labs., Inc., CIV. No. 10-6108, 2012 WL 3133943 (D.N.J. July 30, 2012), in which the Court found lack of diligence as it pertained to a prior art search that was fully in the hands of Defendants, Shire controlled the timetable and withheld key documents, thereby preventing Defendants from asserting the on-sale bar defense earlier in the case.

⁴ Judge Waldor’s opinion noted that: “The parties appeared before this Court on August 1, 2013, an event in between Defendants’ newly discovered information and their formal request to supplement their invalidity contentions.” (D.I. 456 at 6.) Defendants had just formulated their on-sale bar position two days before on July 30, 2013. Further, because Defendants were continuing to seek invoices from AMRI to confirm the on-sale bar, Defendants did not raise the amendment with the Court.

⁵ Shire also argues that Defendants should not have included the on-sale bar defense in their expert reports. (Shire Br. at 2.) Defendants included that defense in their expert reports to

With respect to undue prejudice, it is undisputed that Judge Waldor made no finding as to any prejudice suffered by Shire. While Shire now claims “undue prejudice,” it has not presented specific facts supporting that claim. Shire cannot say that it would be prejudiced if the litigation – and Shire’s monopoly – continued longer. And Shire cannot say that the trial date – which has not yet been set – would be pushed back to its prejudice while it continues to enjoy a monopoly.

In contrast to Shire’s murky claim of undue prejudice, denying the motion to amend Defendants’ contentions would severely prejudice Defendants, and the public, by allowing the validity of the ‘253 Patent to be determined without consideration of the merits of the on-sale bar defense. Dole v. Arco Chem. Co., 921 F.2d 484, 487 (3d Cir. 1990) (explaining that the court should use strong liberality in considering whether to grant leave to amend in order to ensure that a particular claim will be decided on the merits rather than on technicalities); AS Am., 2013 WL 4084237, at *4 (granting motion to amend and citing to Chief Judge Brown’s decision to grant a motion to amend on the eve of trial because “the [Federal Rules of Civil Procedure and Local Patent] Rules should be construed to further the interests of justice.”); Helsinn, 2013 WL 3336859, at *6 (granting motion to amend because “preventing [Defendants] from presenting all of its defenses would not facilitate resolution on the merits.”).

CONCLUSION

For the foregoing reasons, Defendants respectfully ask the Court to reverse D.I. 456 denying Defendants’ Motion to Amend with respect to the on-sale bar defense.

Dated: January 28, 2014

Respectfully submitted,

maintain the schedule entered by Judge Waldor on October 3, 2013 (D.I. 403), and to comply with their statutory obligation to expedite the action, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

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CERTIFICATE OF SERVICE

I hereby certify that on January 28, 2014, true and correct copies of Reply Brief in Support of Defendants' Notice of Appeal Pursuant to L. Civ. R. 72.1(c)(1) was served on all counsel of record via the Court's ECF System and electronic mail.

Dated: January 28, 2014

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